

# Can We Prevent **AV Block** After **CoreValve** Implantation?

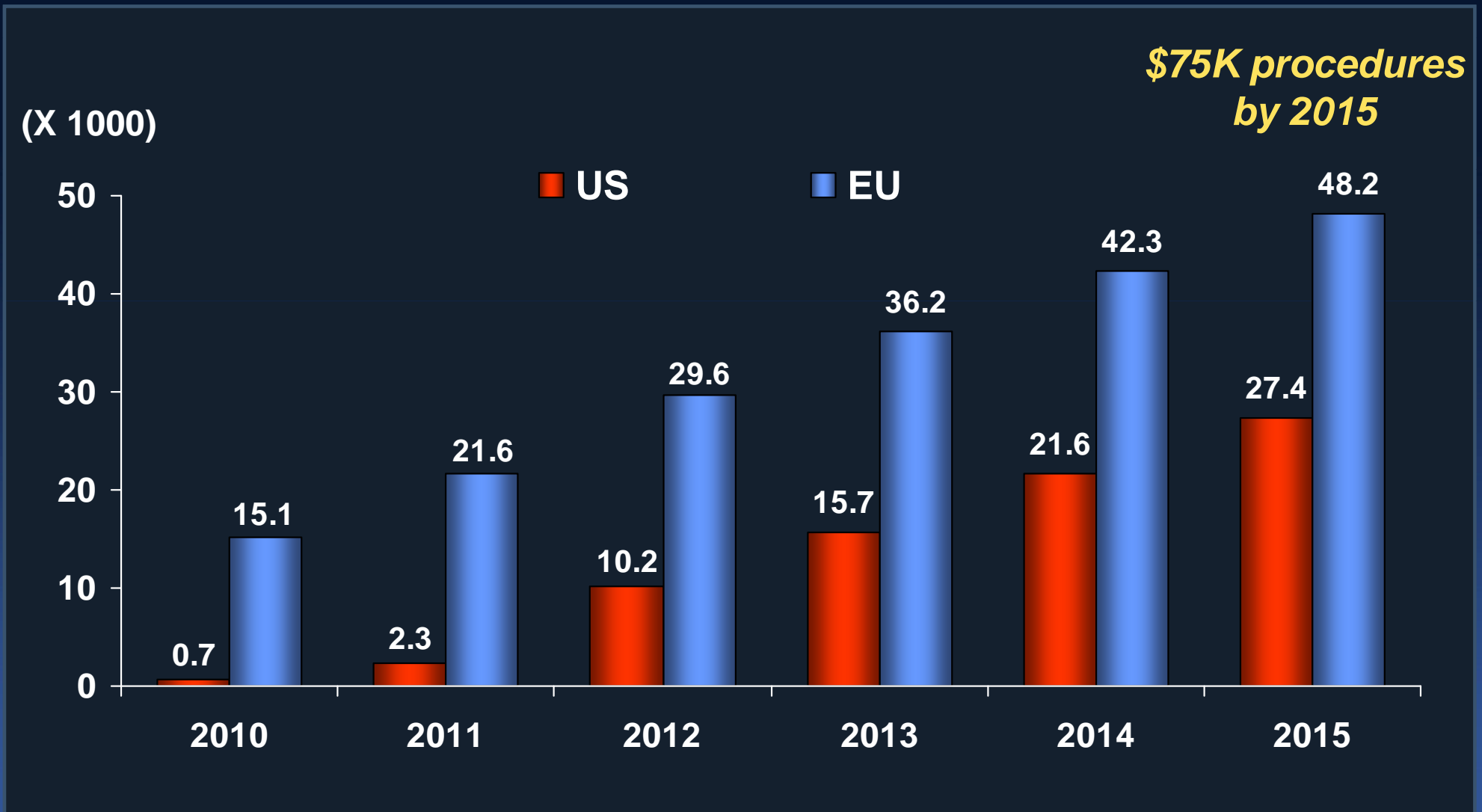
**Won-Jang Kim, MD, PhD**

University of Ulsan College of Medicine,  
Heart Institute, Asan Medical Center, Seoul, Korea

# TAVI, Change of Conception Leading Theme !



# Estimation of Rapid Growth



Courtesy of Mike Weinstein; J.P. Morgan

# Current Status of TAVI in AP

## Feb 2010 to Mar 2013

	<b>CoreValve 116</b>
<b>AMC</b>	36
<b>YUMC</b>	20
<b>SNUH</b>	17
<b>QEH, HK</b>	21
<b>St. Luke, Phil</b>	18
<b>CGHMC, Phil</b>	4

# Baseline Characteristics

	AP	ADVANCE	FRENCH 2			PARTNER		SOURCE	
Design	Registry	Registry	Registry			RCT		Registry	
Treatment	Core	Core	Total	Edw	Core	Edw(B)	Edw(A)	Edw (I)	Edw (II)
No.	116	162	3195	2107	1043	179	348	1038	1269
Age, yr	81	81	82.7	82.3	82.5	83.1	83.6	81.2	81.1
Male, %	37	49.4	51	46.6	48.5	45.8	57.8	44.5	41.3
STS score	-	-	64	58	-	11.2	11.8	-	-
EuroSCORE,%	20.2	19.2	21.9	22.2	24.7	26.4	29.3	27.6	25
NYHA, III,IV,%	97.8	79.6	75.9	75.5	76.1	92.2	94.3	-	-
CAD, %	52.2	57.6	47.9	48.7	46.9	67.6	74.9	-	-
Prior MI, %	1.6	16	16.4	17	15.0	18.6	26.8	-	-
Prior CABG, %	2.2	21.4	18.2	18.2	18.1	37.4	42.6	-	-
Prior Stroke, %	0	-	10	10	10	27.4	29.3	5.5	6.1
Prior PCI, %	32.6	31.1	-	-	-	30.5	34	-	-
Prior BAV, %	-	-	-	-	-	16.2	13.4	-	-

# Results

## Echocardiographic Findings

	<b>Baseline (N=109)</b>	<b>Immediate (N=101)</b>	<b>1 month (N=87)</b>	<b>6 months (N=31)</b>	<b>1-2 year (N=21)</b>
LVEF, %	59.6±10.5	63.6±7.6	62.2±7.7	61.5±7.7	63.1±3.8
AV area, cm <sup>2</sup>	0.65±0.16	1.45±0.33	NA	NA	NA
Mean PG, mmHg	59.9±20.3	15.9±5.3	15.9±7.3	15.2±7.0	16.3±6.3
Peak PG, mmHg	100.3±32.6	29.9±9.8	29.3±11.2	29.4±13.0	30.8±10.8
Mod-sev AR	5 (64.6%)	6 (5.9%)	6 (6.9%)	-	-
Paravalvular leak	NA	Mild-Mod	Mild-Mod	Mild	Mild
Mod-sev MR	3 (4%)	1	1	1	1
Mod-sev pul HTN	0	0	0	0	0

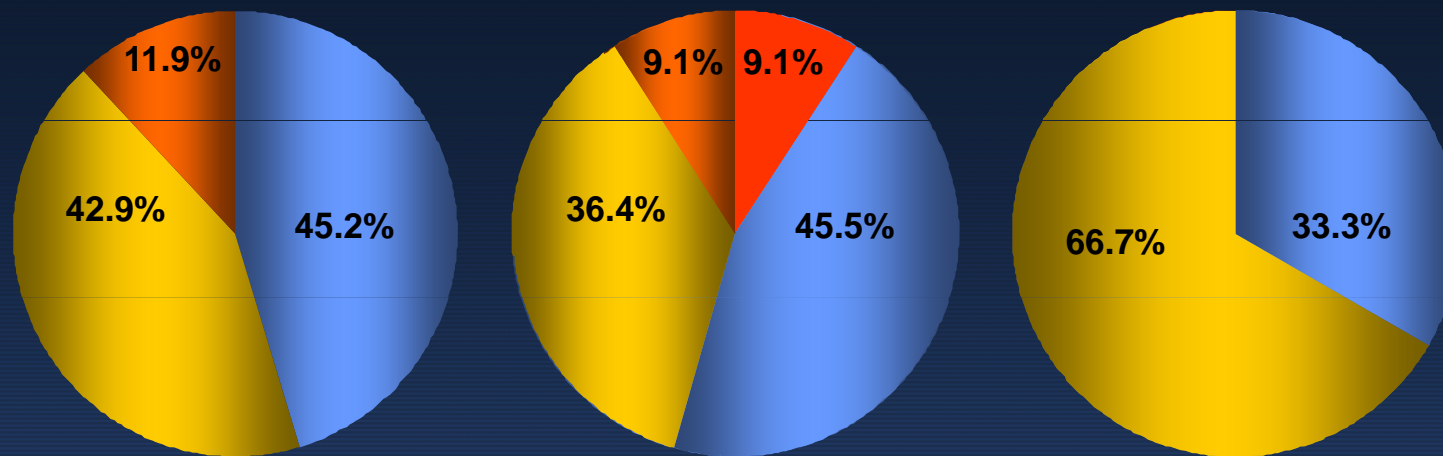
# Mean Gradients Over Time



# Paravalvular Regurgitation

## CoreValve

*Higher Frequency of PVL, but Not Significant !*



1 Month

6 months

1 Year



None/Trace



Mild



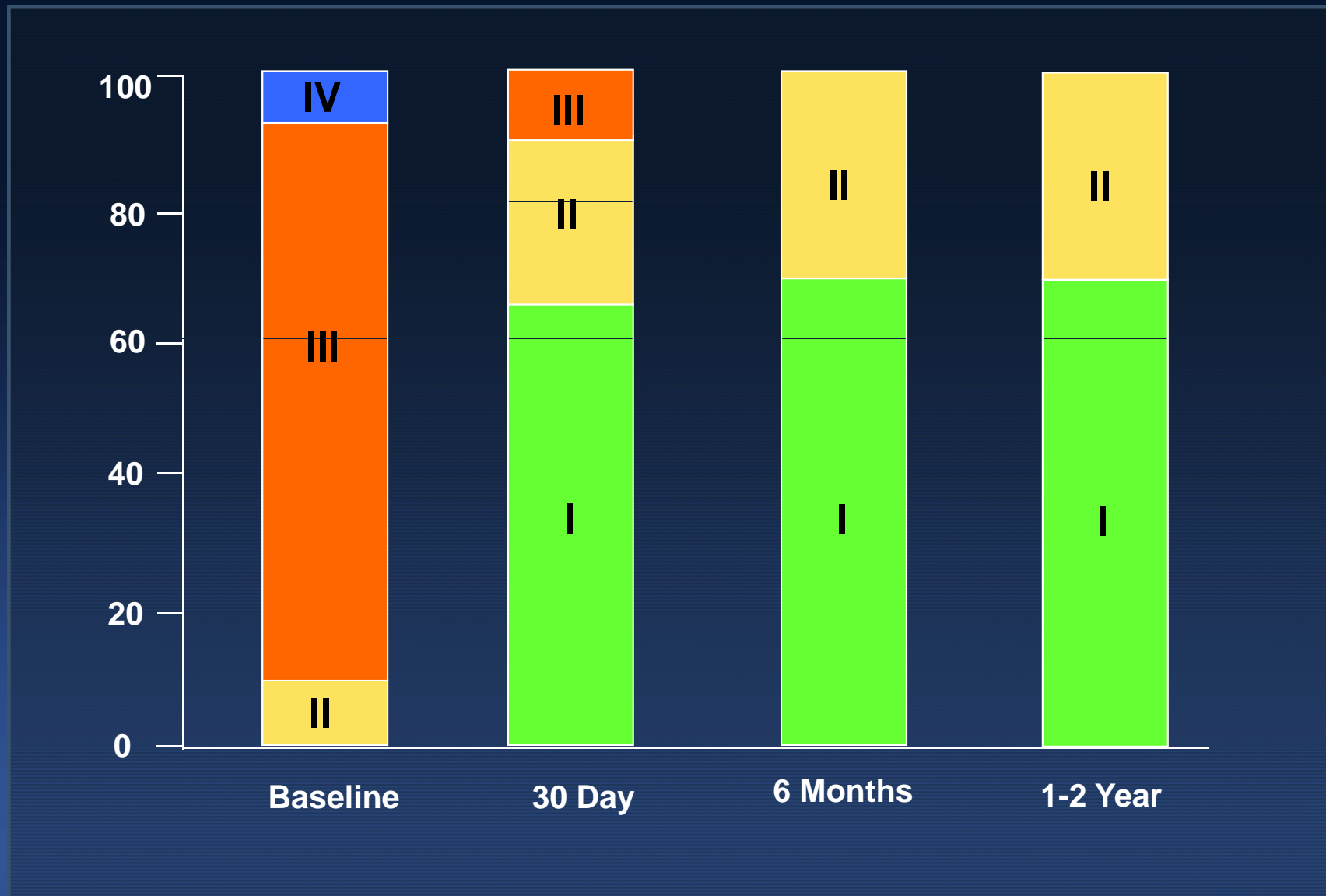
Moderate



Severe



# Subjective Symptom: NYHA



# Procedural Results

	<b>CoreValve (n=116)</b>
Valve Size,mm	
26	54
29	50
31	12
Transfemoral	107
Percutaneous	107
Transapical	0
Direct Aortic	6
Subclavian	3

# In-Hospital, 30 days

	<b>CoreValve (n=116)</b>
Procedural Success	100%
Mortality	5 (4.3%)
Cardiovascular Death	1 (0.9%)
Major or Minor Stroke	0
Permanent Pacemaker	23 (19.8%)
Vascular Complication	0
Access site	0
Iliac Perforation	0

# Follow up

## Median 6 months

	CoreValve
No.	116
Mortality	11 (9.5%)
Cardiovascular	1
Bleeding	2
Sepsis	3
Readmission	2
Mitral valve endocarditis	1
Heart failure exacerbation	1
Aspiration pneumonia	0

# Comparison

Endpoints	Pooled Estimates (%)	AP
Log Euroscore	22.8	22.1
Age, yrs	81.5	79.1
Female	52.0	63.2
NYHA 3 or 4	82.0	98.7
AVA, cm <sup>2</sup>	0.61	0.65
Mean gradient, mmHg	47.6	59.9

\*VARC Meta-Analysis, (16 studies; 3,519 patients)

# Comparison

## Endpoints (%)

## Pooled Estimates

## AP

### Mortality

All at 30 days

7.8

4.3

CV at 30 days

5.6

0.9

All at 1 year

22.1

-

CV at 1 year

14.4

-

### Stroke

Major at 30 days

3.2

-

### Perm Pacemaker at 30 days

CoreValve

28.9

19.8

### Vascular Cx at 30 days

18.8

-

# Lessons from AP Experiences

1. TAVI provides favorable short and mid-term clinical outcomes from 6 center registry.
2. TAVI showed definite objective and subjective improvement in hemodynamics and symptoms.
3. This results would be concordant in survival benefit as accumulation of experiences.
4. We need a **prospective cohort registry**.

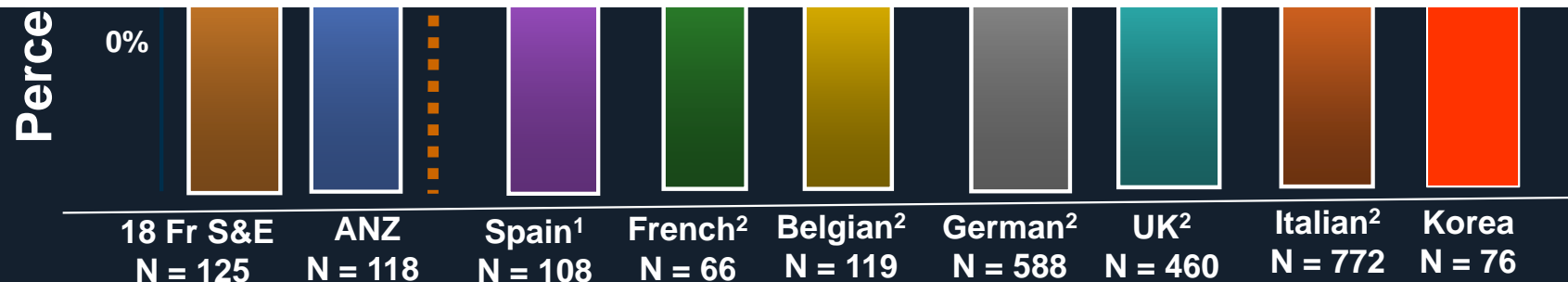
# Predictor Analysis for Permanent Pacemaker



# CoreValve Pacemaker Implantation

## New Pacemaker Implants

“Achilles’ Heel” of  
*CoreValve*



1. Avanzas P, et al; Rev Esp Cardiol. 2010;63:141-148
2. TAVI Facts, Figures and National Registries. EuroPCR 2010

# Main Difference is,

## Perm Pacemaker @ 30 days

Edwards

MDT-Corevalve

*Pooled Estimate (%)*

*[95% CI]*

4.9

[3.9, 6.2]

28.9

[23.0, 36.0]

## Balloon Expandable vs. Self Expanding

VARC Meta-Analysis, (17 studies; 3,519 patients), JACC 2012;59:2297-306

Main Difference is,

**Balloon Expandable**  
**(Volume dependent dilation) vs.**  
**Self Expanding (Gradual Stretching)**

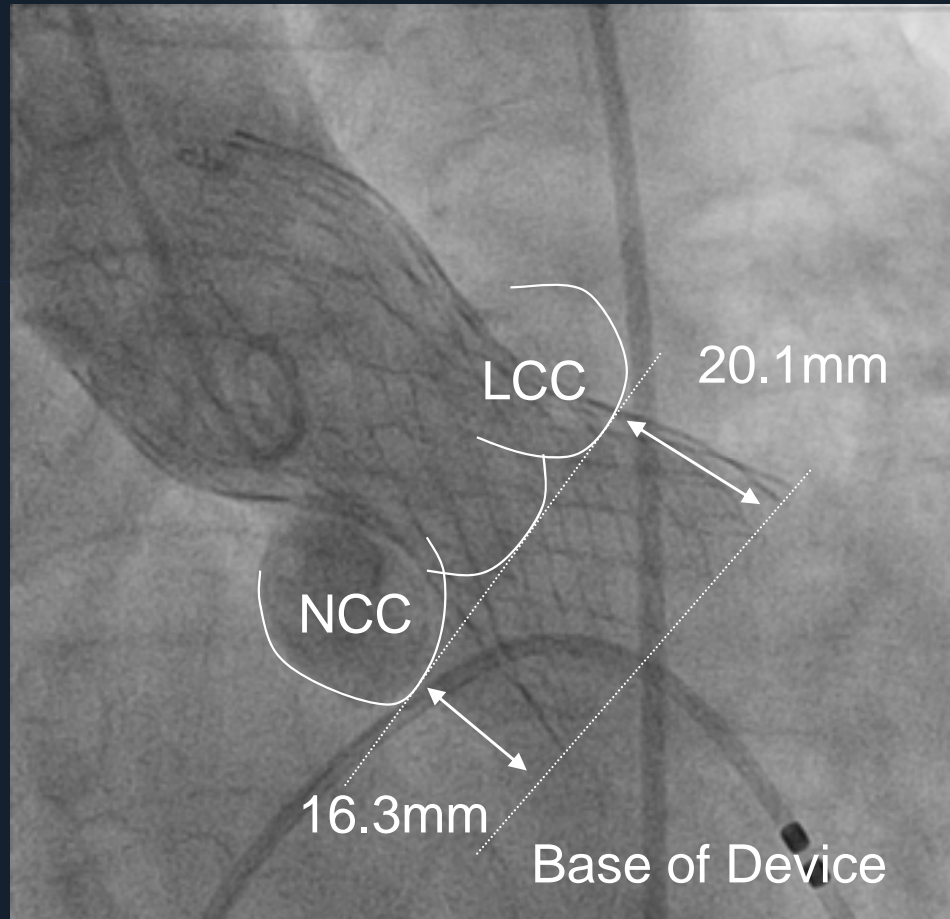
# Predictors for PPM, What Did We Know ?

81/270 pts (33%) permanent PM within 30 days; Median time = 4 days  
Baseline ECG: RBBB 65.2%, LBBB 43.8%, and normal QRS 27.6%

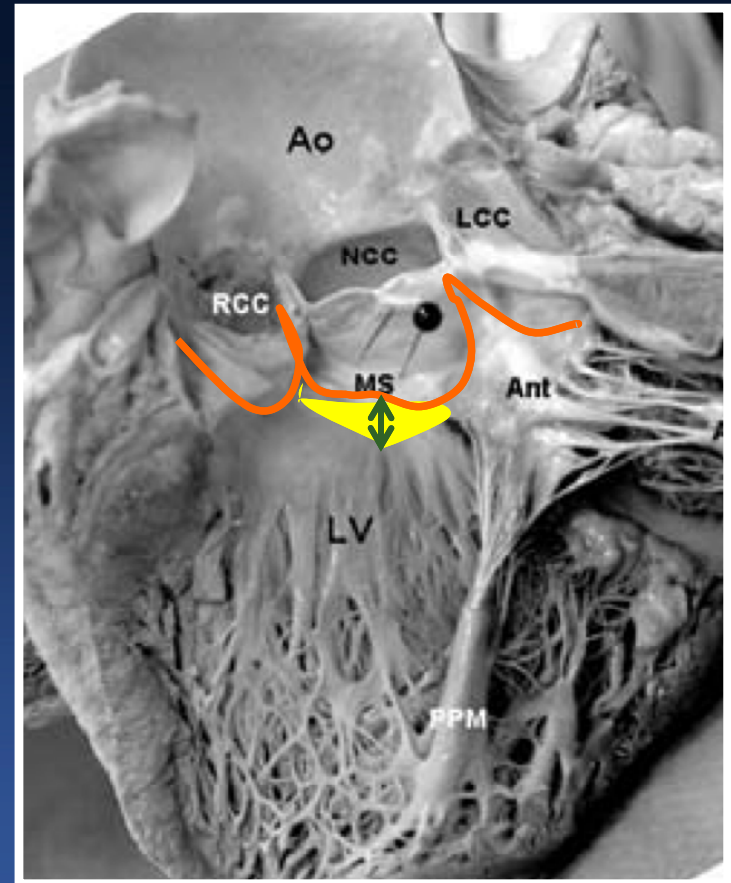
1. Peri-procedural AVB (OR 6.29,  $P < 0.001$ ),
2. Balloon pre-dilatation (OR 2.68,  $P < 0.001$ ),
3. IV septum diameter (OR 1.18,  $P = 0.025$ ),
4. Prolonged QRS duration (baseline) (OR 3.45,  $P = 0.02$ ),
5. Large CV prosthesis (29mm) (OR 2.50,  $P = 0.019$ )
6. Depth of implantation (too low & deep),
7. Calcification several small sized of articles

J Cardiovasc Electoro 2011 (32 articles, 5258 pts analysis)  
*Khawaja et al. Circulation 2011;123:951-60 ( 270 pts analysis)*

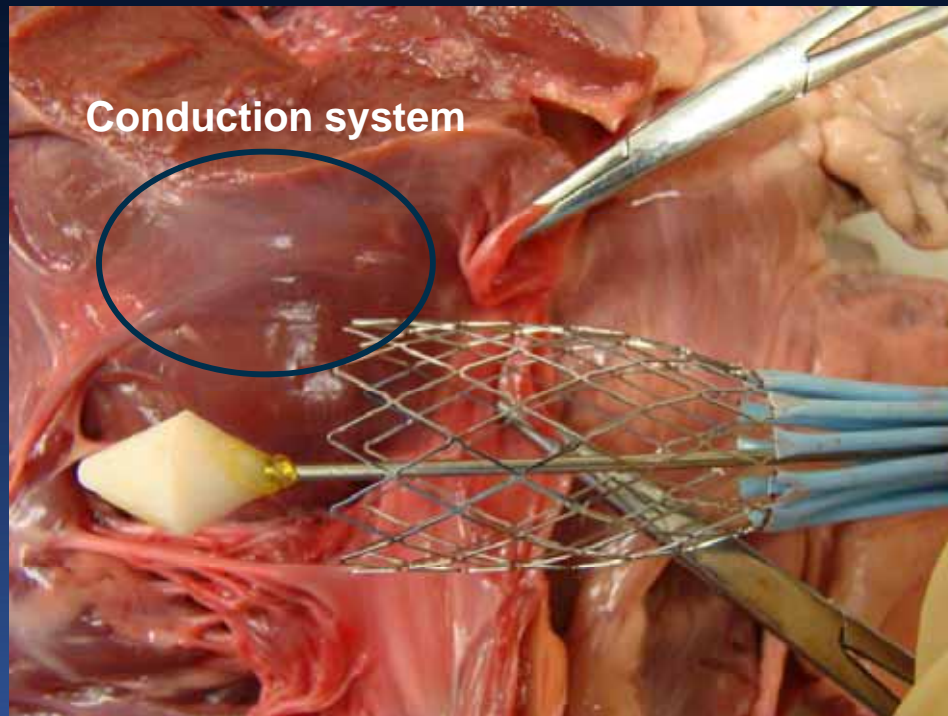
# Depth of Implantation



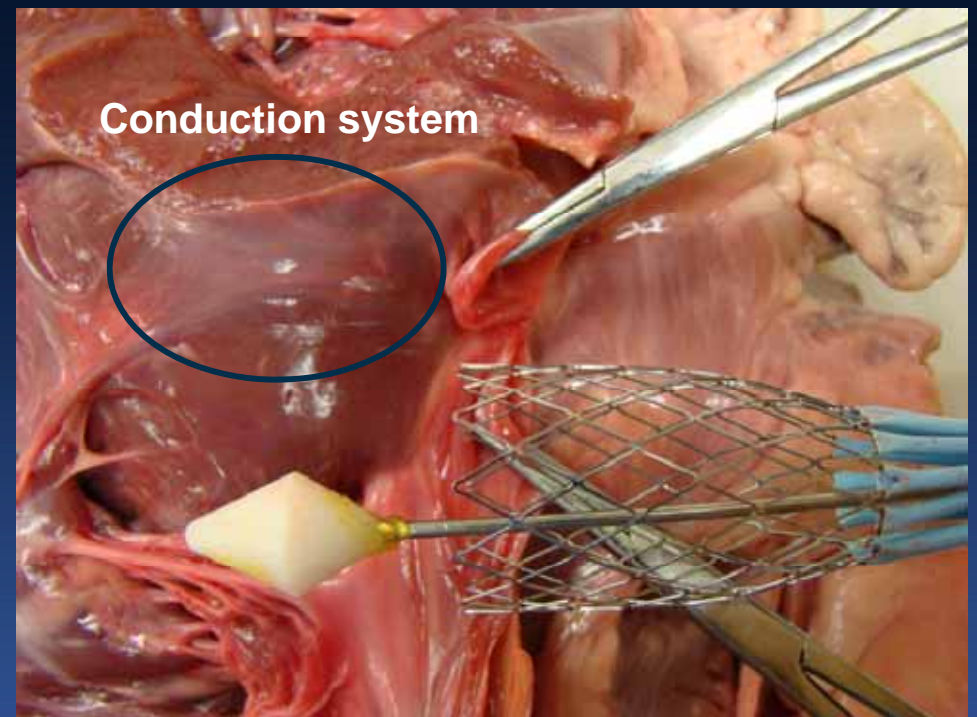
**29 mm with PPM**



# Depth of Implantation



15mm past annulus



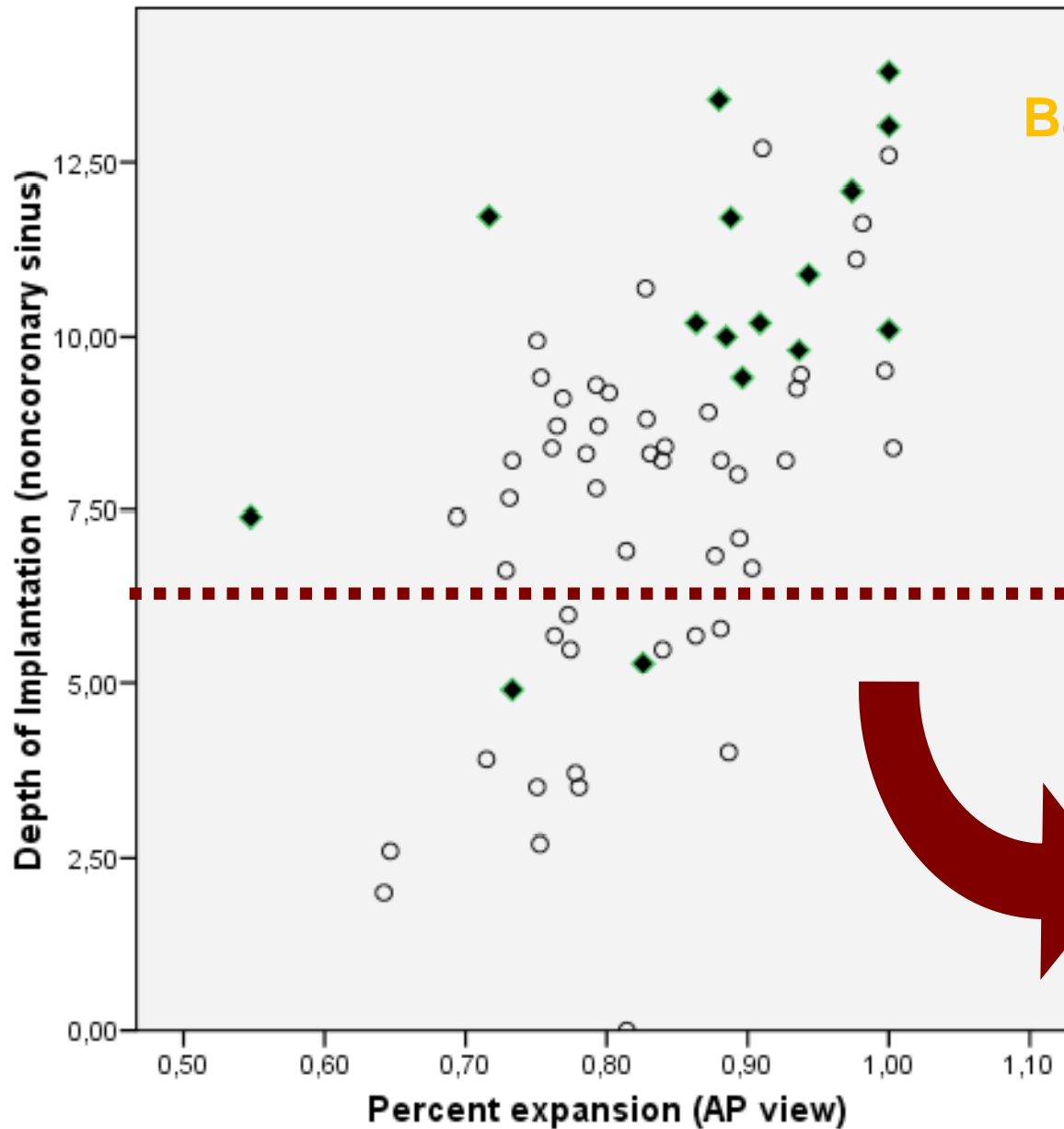
5mm past annulus

Images from porcine heart.




# Depth of Implantation

## Rotterdam CoreValve Experience



 New-onset LBBB acquired during or after valve implantation  
**Baan et al. Am Heart J 2010**

**10.3 mm**  
New-onset LBBB

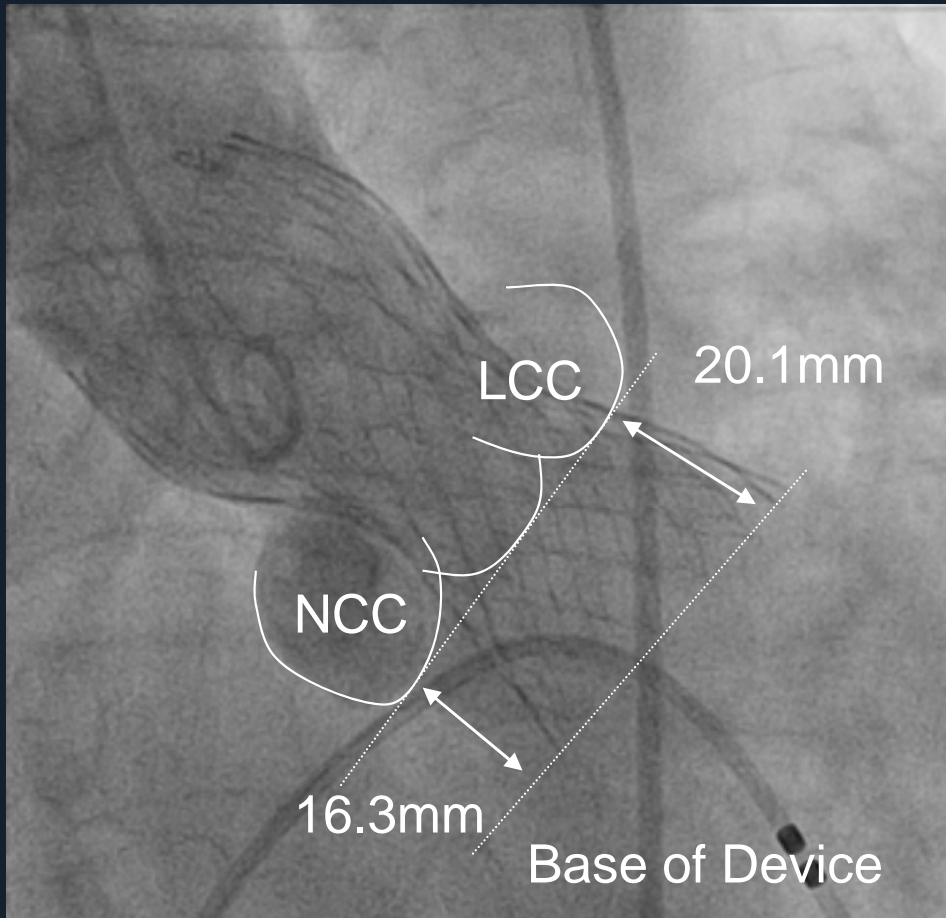
 **10.2 ± 2.3 mm**  
No new-onset LBBB or new-onset LBBB acquired during procedure but before valve implantation

**7.3 mm**  
No new-onset LBBB

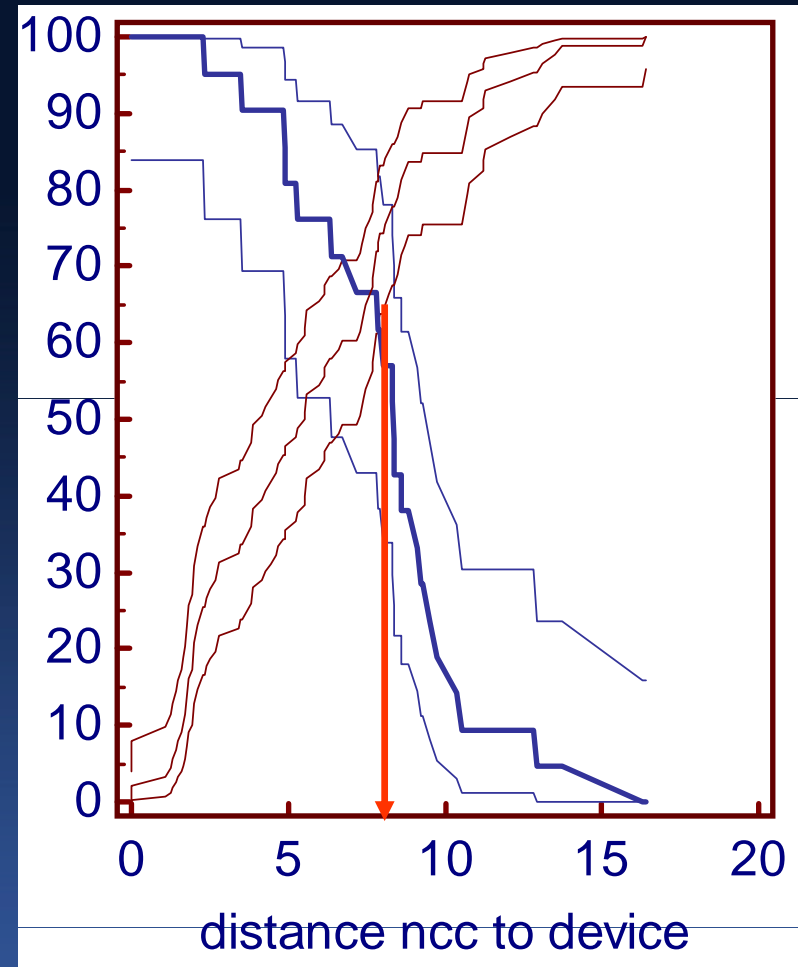
**7.7 ± 3.1 mm**

**6.0 mm**

# Depth of Implantation



**29 mm with PPM**



**7.8 mm**

**Sensitivity 77.8% Specificity 74.4%**

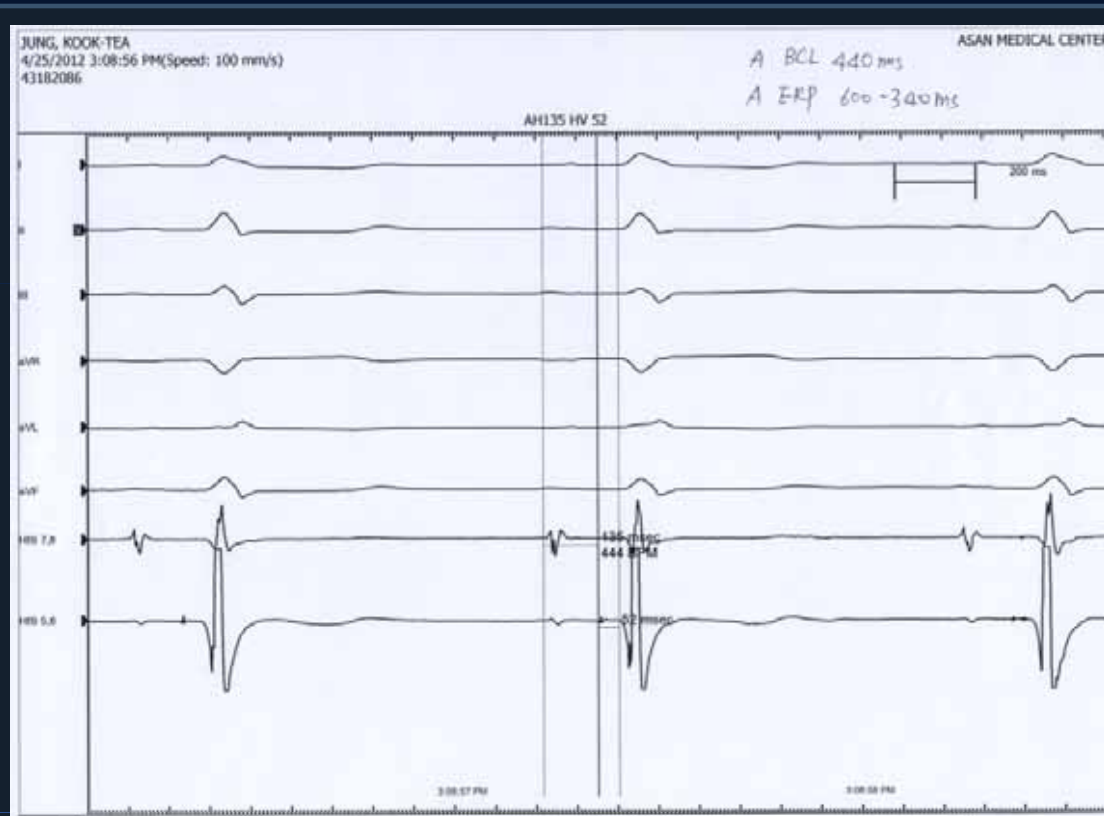
**Accuracy 69.2% OR= 0.125**



# Clinical & Procedural Characteristics

	PPM (+) N=23	PPM (-) N=93	P
Age, yr	83.2±4.2	80.1±4.8	0.08
Male, %	2 (22.2%)	15 (40.5%)	0.45
Euroscore, %	18.8±9.4	20.5±11.5	0.69
NYHA,III,IV, %	7 (77.8%)	29 (78.4%)	0.40
LV EF, %	62.2±4.0	59.5±12.3	0.52
CAD, %	2 (22.2%)	22 (59.5%)	0.06
Prior MI, %	0	0	-
Prior CABG, %	0	1 (2.7%)	1.00
Prior PCI, %	2 (22.2%)	13 (35.1%)	0.69
Prio BAV, %	0	0	-
Prior stroke	0	0	-
<b>Time to PPM implant, day</b>	<b>4.2±3.2</b>	-	-

# His-Bundle Electrogram Immediate After CoreValve



Normal AH 135 & HV 52 ms

Cosecutive 20 pts,  
Same day procedure

Average, (ms)

AH  $130 \pm 4.2$  (Normal 55-125)

HV  $40 \pm 6.2$  (Normal 35-55)

**All patients showed normal  
His-bundle electrogram.**

# CoreValve Complete AV Block

“Delayed Injury” ?

# Delayed Occurring Complete AV Block,

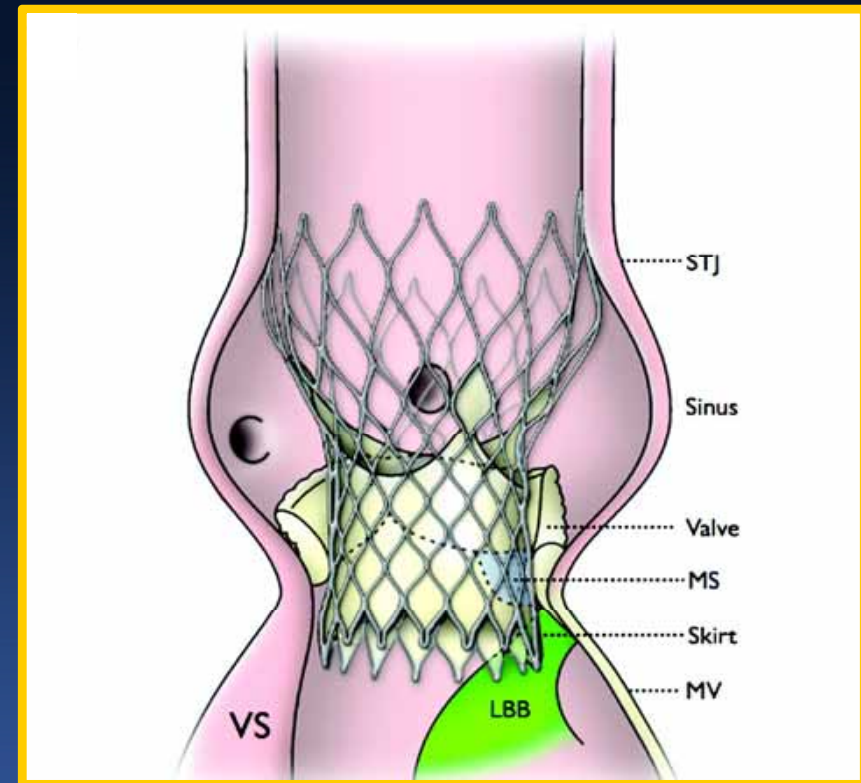
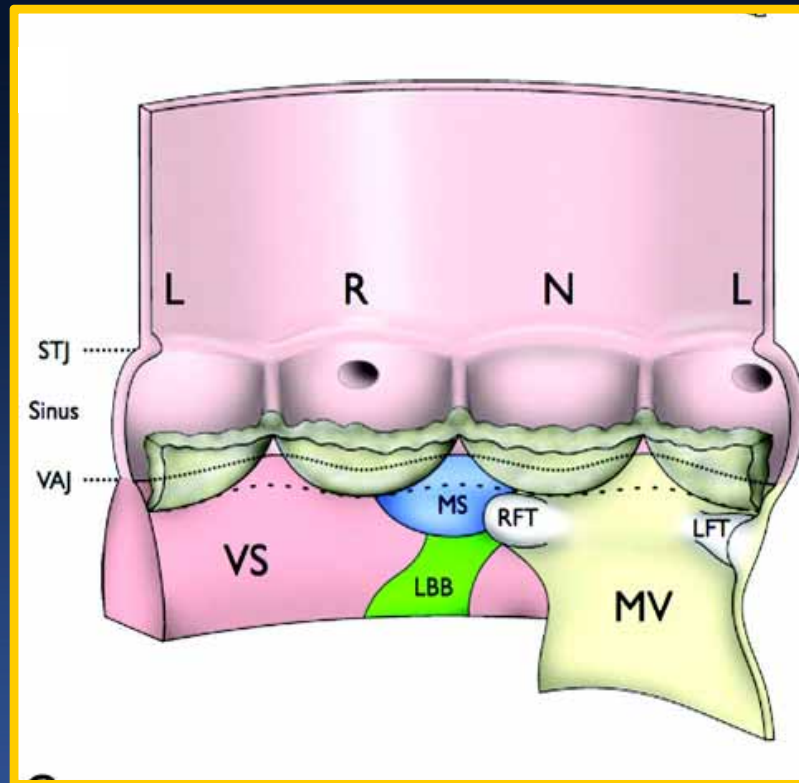
Means,

**Gradual Stretching Injury** of Annulus and  
Conduction System Over Time,

**“Degree of Annulus Stretching”**  
May be Related with CAVB.

# Suggest !

## Delayed Stretching Injury,



Ratio of Device and Annulus Size

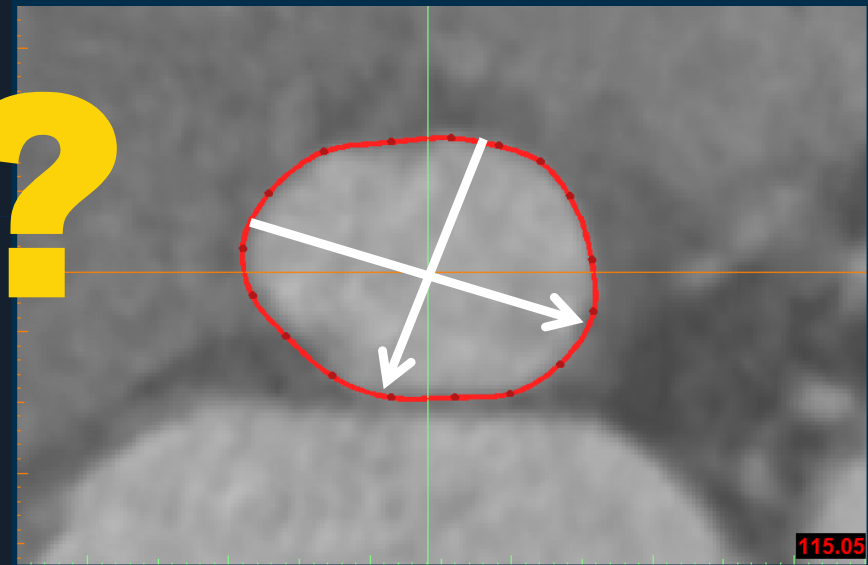
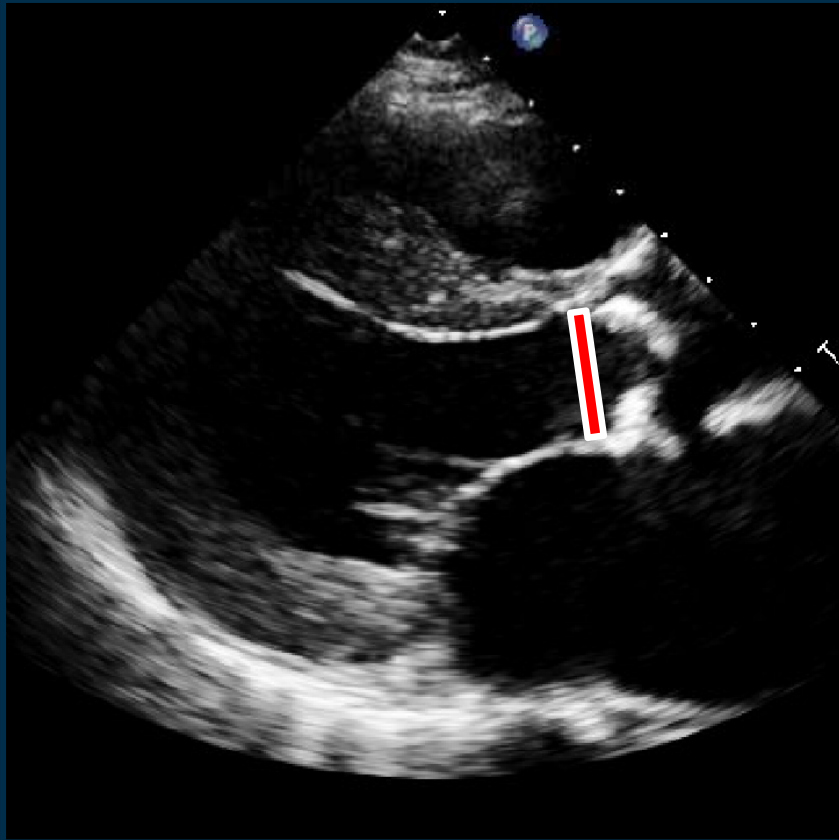
# Guideline, Sizing for CoreValve

<b>Device Size (mm)</b>	<b>Diameter Range (mm)</b>	<b>Perimeter Range (mm)</b>
<b>23</b>	18 - 20	56.5 - 62.8
<b>26</b>	20 - 23	62.8 - 72.3
<b>29</b>	23 - 27	72.3 - 84.8
<b>31</b>	26 - 29	81.7 - 91.1

# How to Measure ?

1. TEE Diameter
2. CT, Diameter
3. CT, Perimeter

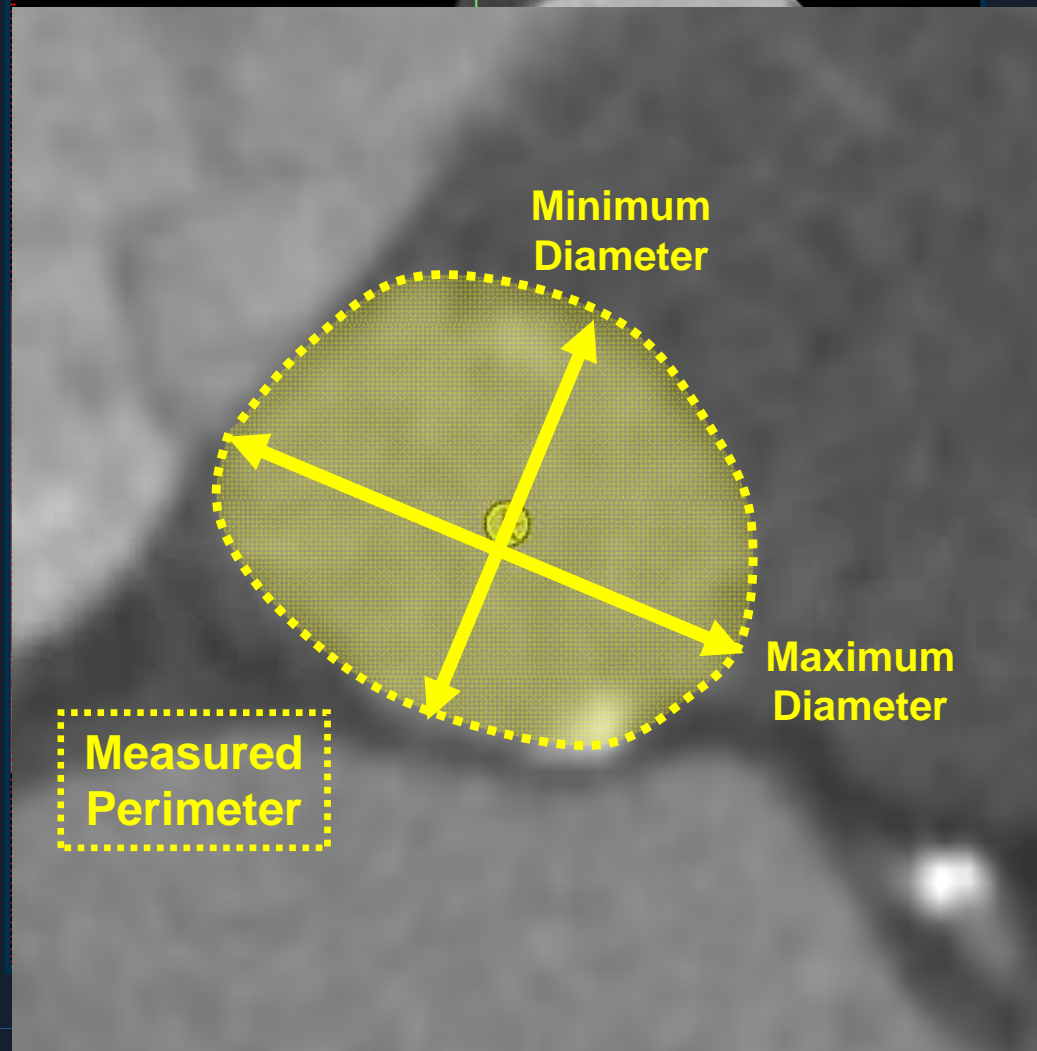
# A Limitation of TEE



Circular annulus is very small proportion. A true diameter may not be measured due to the imaging plane acquired.



# CT Parameters (Diameter, Perimeter)



74.00

# Why Perimeter ?

# Reliability Comparison

## TEE **vs.** CT Diameter **vs.** CT Perimeter (N=30, Preliminary AMC Data)

CT measurements for annulus are usually larger than TEE measurements. **CT perimeter measurements are most reproducible.**

Reliability by ICC (1)	(0.47-0.66)	(0.76-0.94)	(0.84-0.96)	(0.88-0.98)	(0.83-0.97)	(0.86-0.98)
(2)	0.51 (0.40-0.62)	0.93 (0.84-0.97)	0.95 (0.88-0.97)	0.96 (0.89-0.99)	0.93 (0.83-0.96)	0.95 (0.86-0.98)

# Stretching Index

**Device Perimeter (Calculated)**

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**Measured CT Perimeter**

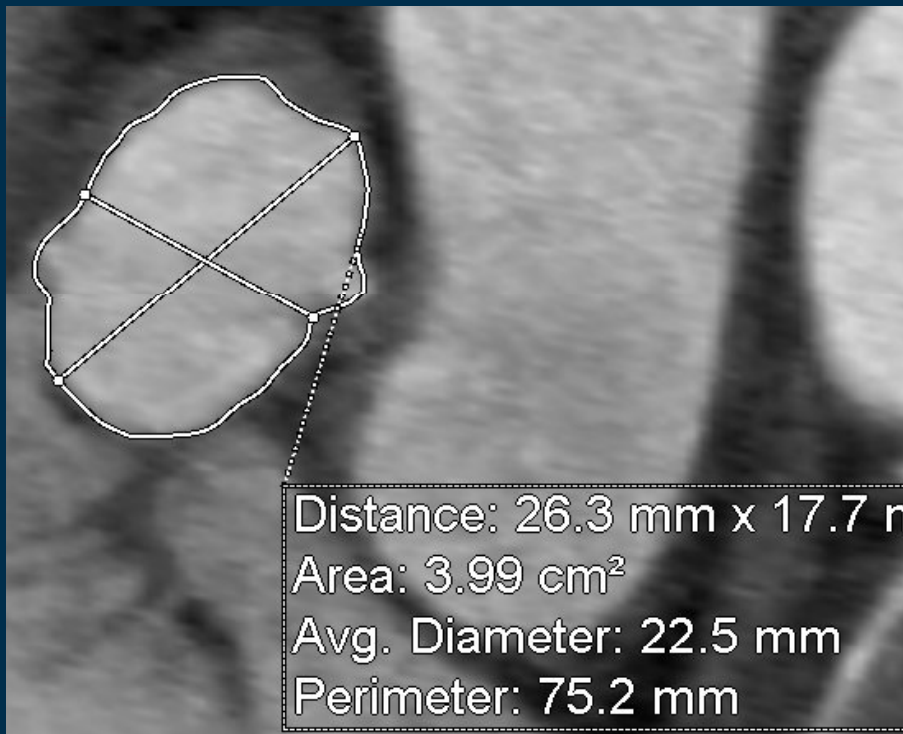
# Guideline, Sizing for CoreValve Using Measured CT Perimeter

<b>Device Size (*mm)</b>	<b>Diameter Range (mm)</b>	<b>Perimeter Range (mm)</b>
<b>23 (72.2)</b>	18 - 20	<b>Measured CT Perimeter</b>
<b>26 (81.6)</b>	20 - 23	
<b>29 (91.1)</b>	23 - 27	
<b>31 (97.3)</b>	26 - 29	

(\*Calculated Perimeter )

# Device 26 mm, **No** Permanent Pacemaker

## Stretching Index



CoreValve, 26 mm  
Calculated Perimeter 81.6 mm

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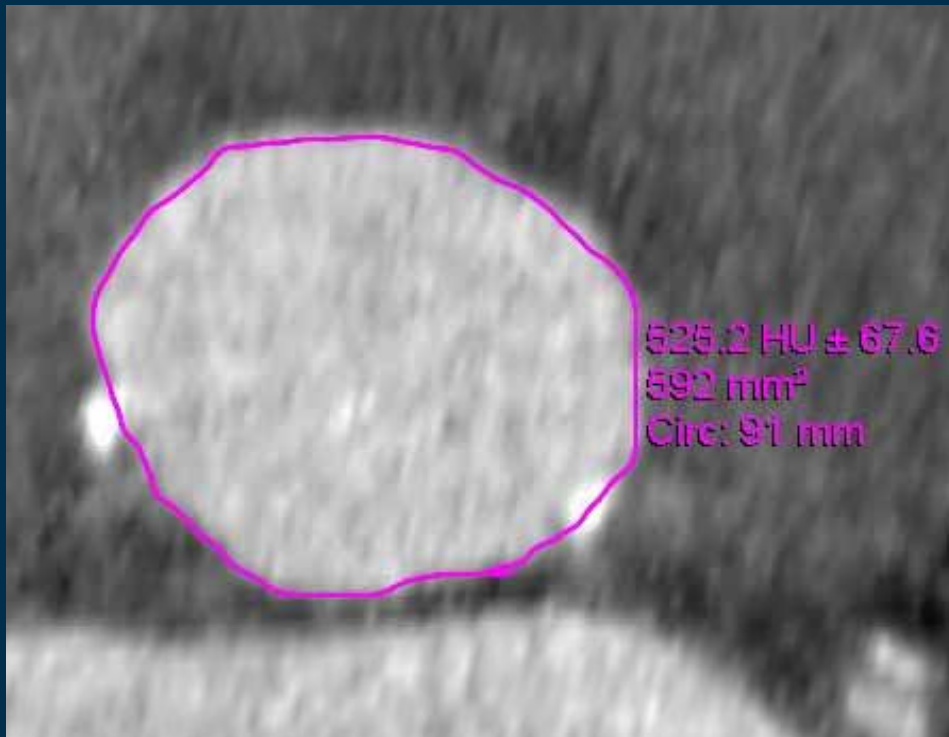
Measured Perimeter 75.2 mm

= 1.09

**Avg. Diameter 22.5 mm (70.6 mm)**

# Device 31 mm, No Permanent Pacemaker

## Stretching Index



CoreValve, 31mm  
Calculated Perimeter 97.3 mm

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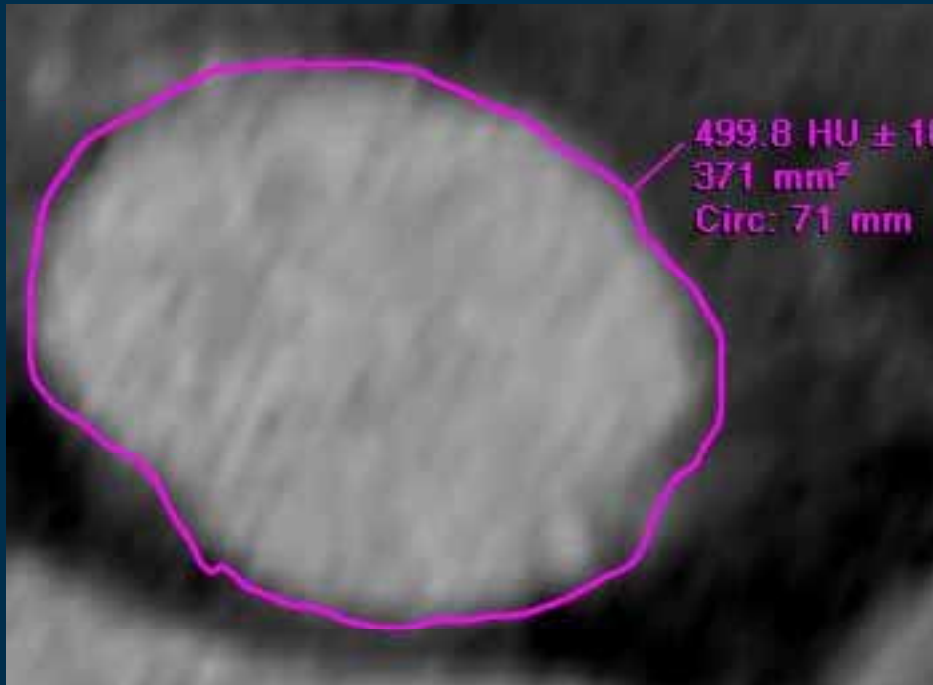
Measured Perimeter 91 mm

= 1.07

Avg. Diameter 26 mm (81.6 mm)

# Device 26 mm, Permanent Pacemaker

## Stretching Index



CoreValve: 26mm  
Calculated Perimeter 81.6 mm

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Measured Perimeter 71 mm

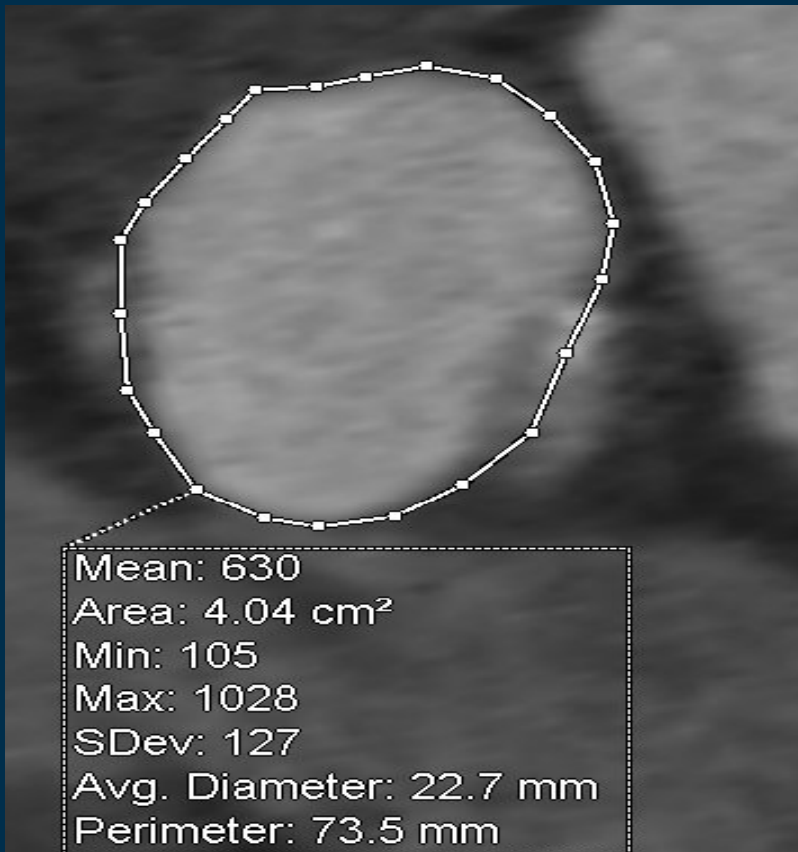
= 1.15

Avg. Diameter 19.6 mm (62.8 mm)



# Device 29 mm, Permanent Pacemaker

## Stretching Index



CoreValve: 29mm  
Calculated Perimeter 91.1 mm

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Measured Perimeter 73.5 mm

**= 1.24**

**Avg. Diameter 22.7 mm (71.3 mm)**

# Predictors for Permanent Pacemaker

Endpoints (%)	Odd Ratio	95% CI	P
Age	1.19	0.92-1.45	0.093
Male	0.42	0.07-2.30	0.32
Large THV (29, 31)	0.34	0.06-1.84	0.21
PR interval, base	1.26	0.97-1.03	0.84
QRS duration, base	1.01	0.98-1.04	0.38
RBBB, base	0.32	0.06-1.73	0.32
LBBB, base	-	-	-
Septum Thickness	1.26	0.85-1.87	0.24
<b>AVA, base</b>	0.018	0.001-0.643	0.028
Block during implant	0.31	0.03-3.29	0.33
Pre-, Postdilation	1.67	0.38-7.29	0.50

# Predictors for Permanent Pacemaker

Endpoints (%)	Odd Ratio	95% CI	P
<b>Implanted depth</b>			
NCC to Device Base	1.23	1.05-1.31	0.01
LCC to Device Base	1.15	1.004-1.31	0.043
<b>Stretching Index with CT perimeter</b>	1.36	1.17-1.57	<0.0001
Stretching Index with CT diameter	1.07	0.91-1.27	0.40
<b>New LBBB</b>	1.00	0.99-1.00	0.63
Calcium, agstone	1.00	0.99-1.00	0.63
Aortoseptal angle	0.98	0.92-1.04	0.43

# Stretching Index **Cut-Off** for Permanent Pacemaker

$$\frac{\text{Device Perimeter (Calculated)}}{\text{Measured CT Perimeter}} > \mathbf{1.134}$$

**Sensitivity**            **83.3%,**

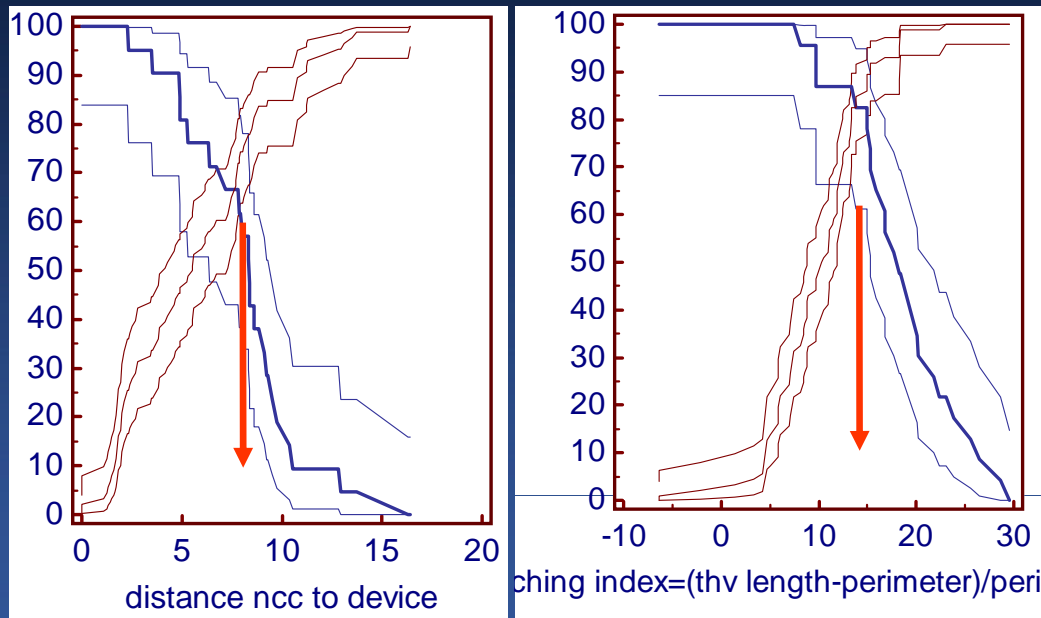
**Specificity**           **81.1%,**

**Accuracy**             **83.5%**

OR 1.359: 95%CI (1.17-1.57): P<0.0001

# 2 Preventable Factors

1. Depth of Implantation
2. Stretching Index



7.8 mm

1.134

**Best Combination**  
**< 7.8 mm and**  
**< 1.134**  
**OR = 0.036, P=0.001**